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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/303,040   | 04/30/1999  | BARBARA J. WINSLOW   | 54957-B/JPW/        | 7815             |
| 27123  | 7590        | 10/26/2006           | EXAMINER            |                  |
| MORGAN & FINNEGAN, L.L.P.<br>3 WORLD FINANCIAL CENTER<br>NEW YORK, NY 10281-2101 |             |                      | HURT, SHARON L      |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 1648                |                  |

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/303,040             | WINSLOW ET AL.      |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Sharon Hurt            | 1648                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05 April 2006.  
 2a) This action is **FINAL**.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 37,41,48,54,58,59,76 and 77 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 37,48,58 and 59 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1)  Notice of References Cited (PTO-892)  
 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3)  Information Disclosure Statement(s) (PTO/SB/08)  
     Paper No(s)/Mail Date Dec. 12, 2005.
- 4)  Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_
- 5)  Notice of Informal Patent Application  
 6)  Other: \_\_\_\_\_

**DETAILED ACTION**

The Examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Sharon Hurt Group Art Unit 1648.

***Response to Amendment***

Amendments to the claims filed April 5, 2006 have been made of record.

Amendment to the title of the invention has been recorded.

Claims 1-36 and 66 have been cancelled. Claims 38-47, 49-53, 55-57, 60-65, and 67-75 have been withdrawn. Claims 37, 41, 58 and 71-72 are currently amended.

Claims 78-82 were newly added in the amendment filed April 5, 2006. Newly submitted claims 78-82 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claimed invention is drawn to a recombinant virus and a vaccine comprising the recombinant virus. The new claims added in the amendment are drawn to a vector comprising an isolated nucleic acid and a host cell comprising the vector. A vector is structurally different and distinct from the recombinant virus of the instant claimed invention. The new claims also include another nucleic acid sequence, which would require a separate search.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 78-82 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 37, 41, 48, 54, 58-59, and 76-77 are under examination on the merits.

***Response to Arguments***

***Rejections Withdrawn***

The rejection of claims 37, 41, 48, 54, 58-59, and 76-77 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn pursuant to applicant's amendments.

***Rejections Maintained***

The rejection of claims 58-59 under 35 U.S.C. 112, first paragraph, as lacking enablement for a vaccine is maintained. Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that "the instant invention describes how to make and use vaccines comprising a recombinant virus having at least one foreign nucleic acid inserted within a viral genome, including foreign nucleic acid encoding an expressible feline protein". Applicant further argues that SPV 246 gave partial protection to cats (see, Table 1). However applicant's claims read on any recombinant virus having as little as a single nucleic acid molecule inserted which encodes an amino acid sequence of SEQ ID NO:6. Applicant's disclosure is limited to SPV 246 which has genes encoding FeLV gag, env, feline CD80 in its entirety, and markers. In this instant the recombinant virus can encompass a virus to which the animal is not known to elicit a

protective immune response and could be fatal to the animal. There is no evidence that inserting CD86 into a virus that is ordinarily lethal to the animal will endow the virus with a protective response encompassed by the definition of the vaccine. Thus it is not predictable if the insertion of CD86 into a virus will result in a composition that can be considered prophylactic to be considered a vaccine. Therefore applicant's arguments are not commensurate in scope with the claims.

The rejection of claims 37, 48, and 58 under 35 U.S.C. 102 (a, b, &/or e) as being anticipated by Freeman et al. (U.S. Patent No. 6,723,705), Freeman et al. (U.S. Patent No. 5,861,310) or Freeman et al. (WO 95/03408; WO) **is maintained**. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that "none of the cited publications anticipate the recombinant virus having a foreign nucleic acid encoding a feline CD86 protein having an amino acid sequence of SEQ ID NO:6". Applicant further argues that the references cited do not disclose an identical sequence as the instant invention. However, applicant's claims only require a portion of the sequence, which can be as little as 2 amino acids of the sequence. Thus, the art anticipates the instant claimed invention. Therefore applicant's arguments are not commensurate in scope with the claims.

The rejection of claims 37, 48, and 58-59 under 35 U.S.C. 103 (a) as being unpatentable over Freeman et al. (U.S. Patent No. 6,723,705), Freeman et al. (U.S. Patent No. 5,861,310) or Freeman et al. (WO 95/03408; WO) in view of Tripathy

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(Advances in Veterinary Medicine, 1999) is maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant's noted that claim 56, rejected in the previous office action has been withdrawn, so assumed the Examiner intended to reject claim 59.

Applicant argues that none of the Freeman references teaches the CD86 molecule in a viral vector. Applicant furthers argues that the Tripathy reference teaches the use of swinepox viral vector for introducing foreign genes for vaccination but "does not remedy the deficiencies of Freeman". Applicant concludes that one skilled in the art would not have a "motivation to alter the human nucleic acid of Freeman and insert the nucleic acid in a swinepox vector to result in a recombinant virus with at least one foreign nucleic acid inserted, where the nucleic acid encodes a feline CD86 protein of the claimed invention".

Freeman et al. does teach the feline CD86 as stated above and for reasons of record. Tripathy teaches the use of a swinepox virus as a vaccine vector as a method of introducing foreign genes into an animal. Examiner maintains that it would have been obvious to insert a CD86 molecule into a viral vector for the purpose of vaccinating an animal.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on a combination of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Claims 41, 54, and 76-77 are free of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Hurt whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

October 16, 2006

*Brenda Brumback*  
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